

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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PRODUCTION VOLUME AND ITS ROLE
IN RISK-BASED INSPECTION

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A CHARGE FROM FSIS: QUESTIONS FOR
CONSIDERATION IN BREAKOUT SESSIONS

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GREEN GROUP BREAKOUT

+ + + + +

April 25, 2007
10:45 a.m.

George Mason University
Arlington Campus
3401 Fairfax Drive
Room 253
Arlington, Virginia 22201

MODERATOR: DR. MICHAEL L. RYBOLT
National Turkey Federation

PARTICIPANTS:

ELLYN BLUMBERG
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MS. TRACY AYERS
DR. PAT BASU
MR. RICHARD BROWN
MR. KEVIN MEAD
MR. STANLEY PAINTER
MR. RICK ROOP
MR. PETER VARDON
MR. CHRIS WALDROP

I-N-D-E-X

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1 P-R-O-C-E-E-D-I-N-G-S

2 (10:45 a.m.)

3 DR. RYBOLT: As everybody knows, I'm Michael
4 Rybolt. The Agency called and asked for somebody to
5 help facilitate one of the groups, and I guess I was
6 designated. It sounds like I was the only one that
7 was called. I guess I was tricked into doing this
8 job. Otherwise, I'd rather be sitting down, but I'm
9 not going to dictate or lead the group. I'm just
10 going to be up here to facilitate the group. So it's
11 really -- we'll go through the questions that were
12 asked that are on the questionnaire, I mean the Agenda
13 that you have here. We'll go through them. They're
14 also written on the board here. I'm not sure who --
15 did you write them? Someone wrote them up for us.
16 We'll talk about the different questions.

17 So I guess at this point, I'm just going to
18 open it up.

19 MR. WALDROP: Michael, are you --

20 DR. RYBOLT: For the record, could you
21 please state your name and your affiliation.

22 MR. WALDROP: Sure. Chris Waldrop, Consumer

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1 Federation of America. Were you involved in the
2 Southwest Meat Association Nona Compromise?

3 DR. RYBOLT: The Decatria.

4 MR. WALDROP: The Decatria.

5 DR. RYBOLT: Yes, I was.

6 MR. WALDROP: I just need some sort of
7 clarification to better understand it.

8 DR. RYBOLT: I have a copy here I can hold
9 up.

10 MR. WALDROP: Great. Because on the bottom,
11 it's the establishment control measure, right.

12 DR. RYBOLT: Establishment risk control is
13 on the top.

14 MR. WALDROP: And on the other side is the
15 product inherent risk.

16 DR. RYBOLT: Yes.

17 MR. WALDROP: Is that right? So do the
18 colors represent different levels of volume?

19 DR. RYBOLT: Levels of inspection.

20 MR. WALDROP: Levels of inspection.

21 DR. RYBOLT: This actually demonstrates what
22 we saw in the presentation FSIS had, and it showed the

1 levels of inspection, depending on your product and
2 your inherent risk control, some establishments and
3 Bill Smith articulated this, at the last meeting I
4 think it was, some establishments may not be able to
5 move out of a level 2 inspection. And, you know, to
6 Dr. Raymond's point, I think industry and I don't
7 know, I think everybody should agree on this, that an
8 establishment should have the ability to move
9 depending on the products he makes and his risk
10 control.

11 If he's got exceptional risk control, may
12 produce the riskiest product, he should be able to
13 move. I say he, the plant should be able to move into
14 a different level of inspection based, you know, on
15 the products on the table itself.

16 So that's why we came out with this one
17 here. If you remember in the handout, it has a level
18 2 I believe, level of inspection 2 is the one that the
19 Agency has, and in looking at that, while that makes
20 sense, but it still doesn't allow an establishment to
21 move to a level 1. So why not split this. It makes
22 it a little bit more difficult for somebody that's

1 producing the riskiest product to get down but, you
2 know, they can move the risk control measures.

3 MR. WALDROP: And according to that design,
4 does that put volume strictly in the --

5 DR. RYBOLT: This does not actually factor
6 volume in. It doesn't say how we should do it.

7 MR. WALDROP: Okay.

8 DR. RYBOLT: It basically says this is the
9 outcome.

10 MR. WALDROP: Okay.

11 DR. RYBOLT: This is what the desirable
12 outcome should be. It gives everybody the opportunity
13 to move, good, bad or individual product.

14 MR. WALDROP: So that one doesn't include --
15 doesn't factor volume in?

16 DR. RYBOLT: This was just under the
17 assumption that we would actually talk about volume
18 today, and that this is the desirable outcome.

19 MR. WALDROP: Okay. And this FSIS, the Nona
20 Matrix, I don't see volume in there either.

21 DR. RYBOLT: They're using in their
22 equation. I mean I don't know if Don answered it here

1 wrong, but they're using the same equation they
2 proposed and they're saying the same thing. This is
3 the desirable outcome. That allows the establishment,
4 say a large establishment to move to a different
5 level, but I don't think it -- we don't think it goes
6 far enough. The desirable outcome needs to be
7 something like this.

8 MR. WALDROP: And we have to figure out how
9 we think volume --

10 DR. RYBOLT: How volume should be
11 incorporated based on the presentations we heard to,
12 other concerns that Stan has.

13 MR. WALDROP: Okay. Thank you.

14 DR. RYBOLT: Does that clarify it?

15 MR. WALDROP: That clarifies it. Thank you
16 very much.

17 DR. RYBOLT: Does everybody understand?

18 MR. ROOP: Rick Roop, Tyson Foods. Question
19 number 1, with all the questions in the other room, I
20 was wondering how we were going to address that since
21 we didn't know the details of either compromise, and
22 you just basically substantiated my question. How can

1 we discuss this?

2 I will from my standpoint say that I prefer
3 the Nona Compromise or Decatria Compromise over what
4 was presented by the Agency only in that it does allow
5 the broad spectrum to get into the lowest versus the
6 highest.

7 DR. RYBOLT: Well, maybe that's a question
8 that we need to think about. I mean we don't have to
9 stick to these questions.

10 MR. ROOP: Advantages and disadvantages and
11 not knowing how they're going to work, it's hard for
12 me to comment.

13 DR. RYBOLT: I mean does everybody agree
14 that, you know, the Decatria that an establishment
15 should be allowed to move, good, bad or indifferent.
16 If you have horrible risk control, then you should be
17 -- have more inspection intensity.

18 MR. ROOP: Yes. I would like just to state
19 from Tyson Foods' standpoint that we would agree that
20 a low volume plant should have the opportunity to have
21 the highest inspection level and vice versa, that the
22 highest volume plant should have the opportunity to

1 have the lowest inspection level. We agree with that
2 concept.

3 DR. RYBOLT: Amanda, were you about to speak
4 or --

5 UNIDENTIFIED SPEAKER: I'm sorry.

6 DR. RYBOLT: Were you about to speak or you
7 just --

8 UNIDENTIFIED SPEAKER: No, I --

9 DR. RYBOLT: Oh, okay. Stan.

10 MR. PAINTER: Well, Stan Painter with the
11 National Joint Council. I don't know that I fully
12 agree with what was just stated.

13 DR. RYBOLT: Okay.

14 MR. PAINTER: You know, I think we have to
15 look at the big picture as far as the volume and, you
16 know, if product being produced in a small plant, if
17 it is contaminated, adulterated, whatever, you know,
18 microbial, *Listeria*, whatever, you know, you're
19 looking at a small amount getting out into the public
20 versus a large amount. And, you know, just to say
21 that, you know, because I produce a large amount, I
22 should have more, I should have less, I don't see that

1 that should factor in, you know, fully as part of the
2 inspection process. You know, to say that I'm a plant
3 that produces, you know, 100,000 product a day, I
4 shouldn't have as much inspection, you know, I don't
5 fully agree with the volume portion of it as far as
6 how it's going to be factored in, in making a
7 determination.

8 And I agree with what the representative of
9 Tyson said, you know, we've just been given this
10 approach. So how do we know which one is better than
11 the other one when we've just been given the approach
12 and we've been given a handout that has, you know, a
13 couple of blips on it and, you know, you could ask a
14 question and you see people looking around the table
15 at each other, you know, that they don't really know.
16 And it seems to me that we need to say what this
17 meeting here is all about. We're asking for the
18 people to develop a program for us because we don't
19 know what we're doing.

20 MS. BLUMBERG: So if I say what the details
21 of the approach is -- the specific details I should
22 write down that you want more of.

1 DR. RYBOLT: It sounds like, and I don't
2 know if we have the same sentiment, but it sounds like
3 what we need to know is how is volume, since this is a
4 volume meeting, how is volume factored into the RBI
5 system to allow you to move from either this one or
6 the Nona, whatever, and that's what it sounds like
7 you're asking.

8 MR. PAINTER: Well, as far as my part, I'm
9 not worried about the move, you know, the moving from
10 one category to the other.

11 DR. RYBOLT: It's the same thing as saying
12 how is volume factored into the RBI.

13 MR. PAINTER: That's correct. How do you
14 get where you're going in the beginning and, you know,
15 how do we arrive where we're going to be factoring
16 into the level of inspection?

17 DR. RYBOLT: Right. Now the way that the
18 Agency has volume in their RBI algorithm, it is, you
19 know, as everybody knows, it's the inherent risk times
20 a volume factor and, of course, there's the paper
21 there that explains how to come up with volume factor
22 based on your pounds produced per day and how much is

1 shipped per month, et cetera. So that's how the
2 volume is factored in now on their side, and the way I
3 understand it, is that's how the Nona Matrix, that Don
4 presented, that's what they're proposing to us at this
5 point. They're looking for alternatives and that's
6 one of the things we should discuss here is, you know,
7 Jenny Scott got up and talked about the industry has
8 felt that it should be on the other side of the
9 equation rather than on the inherent risk side. And
10 maybe we won't even answer the questions at all.
11 Maybe we'll just talk about where volume should be on
12 the equation. Is it a function of the inherent risk
13 or is it a function of -- I'm sorry. I keep hitting
14 that, hurting your ears there. Is it more of a
15 function of the establishments? Is volume important
16 at all for RBI?

17 MR. ROOP: Rick Roop, Tyson. I agree with
18 Jenny Scott's assessment of Dr. Harris and also Janell
19 made some comments also that volume although it cannot
20 be considered in determining risk. I believe volume
21 has to be a factor but not a direct factor as it is
22 currently proposed. There's no doubt in my mind that

1 these compromises are taking that into account, and I
2 agree with that approach. How it's factored in, I do
3 not have a suggestion at this point, but it definitely
4 should not be a direct multiplier. Because that just
5 totally negates a plant's ability to control risk.

6 DR. RYBOLT: I think I got right. This is
7 the way the current algorithm looks. Your inherent
8 risk measure times the volume factor and then you add
9 that to the outcome -- risk control measure, and then
10 you add those two together and divide by two, and
11 that's where you get your RBI. I think that's the way
12 they had it, and we can use that as we talk about
13 this.

14 MR. BROWN: Richard Brown with FSIS. Where
15 does establishment complexity fall into that?

16 DR. RYBOLT: Establishment complexity
17 meaning --

18 MR. BROWN: The processes that occur within
19 the establishment. I can't, I can't help, when I
20 think of volume, I automatically think of complexity
21 of the goods they manufacture, the risk and hazard --

22 DR. RYBOLT: Let me go to, so I can just

1 write them up here what's included in this. The risk
2 control measure actually incorporates five different
3 components -- seven different components. I'm sorry.
4 The NRs, the enforcements, *Lm* alternative --
5 *Salmonella* verification, microbe testing, food safety
6 recalls and verified food safety components. Those
7 are the components that go into the RCM, and I don't
8 know if that's actually answering your question or
9 not. This incorporates the complexity.

10 MR. BROWN: I don't see the --

11 DR. RYBOLT: You're talking complexity, the
12 microbial treatments or interventions that are used in
13 establishments?

14 MR. BROWN: Well, I've been in
15 establishments that are very simple that put out a lot
16 of volume but put it out poorly. I've also been in
17 establishments that are very complex with a lot of
18 different kinds of processes, and they don't produce a
19 whole lot of product but they do very well. And, you
20 know, everything in between. So it seems like volume
21 shouldn't have quite so important a status that
22 complexity does.

1 DR. RYBOLT: I think that kind of goes along
2 with we have been, that there's too much is put on the
3 volume factor especially when you include it on this
4 side of the equation. Rick said it, and we agree that
5 volume is something that should be considered but the
6 way the system is now, this side of the equation is 50
7 percent and RCM is 50 percent. And then I don't have
8 the papers but the volume factor is 25 percent of that
9 I think, of that 50.

10 DR. BASU: Pat Basu, APANA. I just want to
11 verify you have IR as a lone factor. I think that's
12 not how it's represented in the paper that was given.
13 The inherent risk is --

14 DR. RYBOLT: It is the inherent risk. I
15 have that wrong.

16 DR. BASU: Volume and hazard together make
17 IRM.

18 DR. RYBOLT: Yes. It should say inherent
19 risk.

20 DR. BASU: Right.

21 DR. RYBOLT: Sorry.

22 DR. BASU: So that makes a difference in

1 what you're saying.

2 DR. RYBOLT: There we go.

3 DR. BASU: No, inherent risk is volume and
4 hazard.

5 DR. RYBOLT: The inherent risk of a product
6 which is based on the expert elicitation times volume,
7 that's how they come up with that.

8 DR. BASU: Okay. It says volume and hazard
9 are incident together and the presentation is on here.

10 DR. RYBOLT: Yes, this come up. This right
11 here comes out to be inherent risk measure. These
12 two, these two --

13 DR. BASU: You're saying volume factor by
14 itself. That's not what it says in the presentation.

15 DR. RYBOLT: The presentation he gave today?

16 DR. BASU: Yes. It says volume and hazard.
17 It makes a difference in how it's represented.

18 MR. ROOP: He's talking about this right
19 here.

20 DR. RYBOLT: Yes, yes, and that's what I
21 have up here.

22 DR. BASU: I don't see it. You're saying IR

1 times volume factor, that's not what it says.

2 DR. RYBOLT: This right here, these two
3 factors come together, you add RCM --

4 DR. BASU: IR is inherent risk.

5 DR. RYBOLT: Yes, inherent risk. So this is
6 from the expert elicitation 1 through 10 or 2 through
7 20, you multiply --

8 DR. BASU: You're missing something. It
9 doesn't say that on here.

10 DR. RYBOLT: He didn't give that today. He
11 talked about that last week.

12 DR. BASU: I mean it doesn't say in the
13 presentation we had today. That's all I'm saying.

14 MR. ROOP: Yeah, but he did, if I recall, he
15 actually said that based on the previous publications
16 and papers or presentations, that's how we're coming
17 up with that. I mean everybody here has been part of
18 the meeting. So --

19 DR. BASU: IR to me is a hazard. That's
20 what he's saying. The IR you're stating is hazard and
21 hazard and volume together become IR.

22 DR. RYBOLT: That's correct.

1 MR. ROOP: The inherent risk, all Mike's got
2 up there, Mike Roop from Hormel -- the inherent risk
3 is -- all he's doing is taking what the hazard rating
4 is off the expert elicitation.

5 DR. BASU: Correct.

6 MR. ROOP: He's calling it IR. The volume
7 and --

8 DR. BASU: Right. It's being called
9 differently --

10 MR. ROOP: 1, 2, 3, 4, 5

11 DR. RYBOLT: So you can just call it the
12 expert elicitation if you want to.

13 MR. MEAD: Inherent risk measure, I think
14 the one thing that, the matrix helps to some degree
15 but I think we're in agreement as well that no where
16 is volume -- if you look at your risk control
17 measures, if a plant has post-lethality treatment,
18 post-packaging lethality treatment, the only place
19 that that comes into play is whether you have 0, 1, 2
20 or 3 points on the *Listeria* alternative. Nowhere does
21 it say maybe your plant produces 50 million pounds but
22 25 million pounds of that has post-packaging lethality

1 treatment which is the best situation for your plant
2 right now. That is not factored in anywhere in the
3 inherent risk control measure.

4 DR. RYBOLT: The interventions.

5 MR. MEAD: Correct. And, you know, neither
6 is say a plant wants to be tested whole on all of
7 their products going out the door, that's not factored
8 into it. There's a lot of things a plant can do from
9 a risk control measure that still is not taking effect
10 anywhere on any of this risk-based inspection models.
11 You know, the matrix helps a little bit because you
12 get rid of the average.

13 DR. RYBOLT: I think that's what Dr. Raymond
14 outlined, I believe he said this and maybe he also
15 said it at the last meeting that, you know, you can
16 establish some sort of credits or whatever if you have
17 programs in place like testing or maybe some sort of
18 intervention that will have a bearing. You could --
19 how that's incorporated but, you know, that's
20 something else that the Agency is looking at. Chris.

21 MR. WALDROP: Chris Waldrop, Consumer
22 Federation. One of the things Jenny Scott said early,

1 not at this meeting but at earlier meetings, was that
2 volume should be maybe a third dimension --

3 DR. RYBOLT: Uh-huh.

4 MR. WALDROP: -- and it sounds like, you
5 know, I didn't talk to her but just from her comments,
6 it sounds like she's now thinking that it should be
7 more a part of the risk control measures.

8 DR. RYBOLT: I don't know if that's going to
9 change in her thinking but that the third dimension
10 kind of made more sense to me than either putting it
11 on one or the other.

12 MR. WALDROP: I don't know. I still don't
13 know how you would actually make that work.

14 DR. RYBOLT: Yeah, that's what -- I think,
15 you know, to that, I think we have tried to discuss
16 how to incorporate volume. We did, we do agree that
17 this is not where it belongs, that it over inflates
18 this side of the equation. And it's actually more of
19 a, as she articulated better than I can, it's actually
20 a function of the risk control measures, and volume
21 should be on this side of the equation.

22 MR. WALDROP: Yeah. She did say before it

1 should be a third but how do you make that happen?

2 DR. RYBOLT: And that's why you need, you
3 know, that's why we're looking at and trying to figure
4 out whether to put it over here. So one of the
5 solutions we talked about is just simply -- and that
6 would have to work -- you would have to work in
7 through the calculations to make sure that the numbers
8 work out and move that over there.

9 MR. PAINTER: Go ahead.

10 MR. ROOP: Rick Roop. One of the ways that
11 you could get credit for the volume based on your
12 interventions and your annual process would be -- and
13 this would be a more complex way of determining volume
14 of a plant, but each product type would be -- the
15 volume of each product type would be considered at a
16 different level. In other words, for post-package
17 pasteurization product, if you have 1 million pounds a
18 week of that product, it would be 1 million pounds
19 times 25 percent or some factor. If you have one that
20 receives no intervention whatsoever, it would be
21 considered at 100 percent. And so by the time you end
22 up with the total volume of the plant, it would "add

1 that credibility" into the volume factor and it would
2 not require changing the original formula.

3 DR. RYBOLT: Okay. The way they have, if
4 you look at the mean expert elicitation values that's
5 in the inherent risk measure paper, within that, they
6 actually -- you get your IR from that table and some
7 of the categories they have is RB fully cooked without
8 subsequent exposure to environment and then RB poultry
9 meat without subsequent exposure to the environment.
10 But it does --

11 MR. ROOP: Correct.

12 DR. RYBOLT: So they do have some part of
13 it. It's not the complete picture there, and then
14 once you get that number you use the volume multiplier
15 that come up in the paper, times that particular
16 product is the inherent risk and you get a total on
17 the different products and then you get a total -- on
18 this whole side here. Again --

19 MR. PAINTER: Stan Painter with National
20 Joint Council. And I feel it's appropriate to say
21 that as a group and as part of this group, I want to
22 take something that you said earlier, when you said I

1 sound as though I'm speaking as an Agency
2 representative, although I'm not. In my opinion, we
3 need to be extremely careful here because we've got to
4 be careful what we ask for or we might get it because
5 whatever comes out of this group, and the Agency puts
6 it into place, they they're going to say, that's what
7 came out of the group, that's what you asked for, YXX
8 Poultry, or that's what you asked for, you know,
9 Midwestern Meat Producers, whatever. Or the
10 inspectors, that's what you asked for and you've got
11 it and now you're going to have to live with it.

12 So in my opinion, we need to be extremely
13 careful here what we suggest and that we're able to
14 live with what we decide that we want to do or what's
15 going to be our group comment.

16 DR. RYBOLT: Does someone want to volunteer
17 to -- I was just asked to facilitate. I wasn't asked
18 to be a snitch.

19 MR. PAINTER: Stan Painter again. I'm going
20 to be honest with you. I didn't come to this meeting
21 to fix the Agency's problem. You know, I come to be
22 informed. I come to hear what's going on. I came to

1 give comments. I didn't come to fix a problem. They
2 came up with this approach. I didn't come up with
3 this approach. I don't ask them to fix my problems,
4 you know, they're asking us to fix something that
5 they've now developed. They've produced the car. Now
6 they can't get it to run, and then they want us to get
7 the car to run. So I'm not in a position of fixing
8 their problems.

9 DR. RYBOLT: So it looks like the first two
10 questions, I don't know that it has the first
11 comments, I'll just note it on the board. They don't
12 have details of the specifics with Nona or the
13 Decatria. So we don't know if we can answer either,
14 but we come to this question, number 3. What specific
15 records should the inspectors use to approximate
16 volume for various product categories in these
17 approaches, which going back to the approaches, but
18 take that out of the -- what are some tools that can
19 be used.

20 MR. PAINTER: I've got a lot to say on that.
21 And it's not -- well, maybe it's not clear, is it the
22 volume produced or the volume of inspected product

1 produced?

2 Now we have a lot of plants, a lot of
3 poultry plants that sell the chicken feet or the claws
4 to a lot of companies in the Orient, China, Korea,
5 places like that. Those are not inspected products
6 but are products that are packed and produced. We
7 certify, the USDA inspector is there, packed and
8 produce under wholesome conditions. So, you know, the
9 question I had does that add to the volume because
10 it's not inspected product but it is product produced.
11 So are we looking only at a volume that a person would
12 have to keep up with that would be an inspected
13 product or every product prepared?

14 DR. RYBOLT: Dr. Engeljohn just came in on
15 that. He would be the perfect person to answer the
16 question. Going back to Stan's question earlier about
17 the production of volume or products shipped, he
18 actually mentioned products like claws, not inspected
19 but certified. Do that count into this or is it only
20 -- what is the volume that we're talking?

21 DR. ENGELJOHN: Anytime product is produced,
22 it's produced when the shipment clearance records are

1 completed. So when that's done, the product is
2 produced. So that's the product that we're talking
3 about regardless of whether it went into storage or
4 not, but if the issue is, it can be clarified to say,
5 you know, the Agency asked the question at this plant,
6 particularly if it's in cold storage or things, you
7 know, we can ask those kinds of questions. We're
8 really interested in what product is available in
9 commerce is really what the question is.

10 MR. ROOP: So it would be inspected product?

11 DR. ENGELJOHN: Yes. Inspected and packed
12 product. In essence --

13 MR. ROOP: For shipping or --

14 DR. ENGELJOHN: That is technically what is
15 produced and shipped. It may still be in the plant
16 but --

17 DR. RYBOLT: Is that --

18 MR. PAINTER: Let me make sure he understood
19 my question. Chicken claws, chicken feet, they're not
20 inspected product. They're not entered into the
21 volume. That's what you're saying, correct?

22 DR. ENGELJOHN: Yes.

1 DR. RYBOLT: Dr. Engeljohn walked in after
2 we had started trying to address question number 1,
3 what are the advantages and disadvantages of each
4 approach, and I think, and correct me if I'm wrong, I
5 think everybody said that we don't have enough details
6 on how these particular models, the Nona, that Joe
7 talked about and that Don talked about, you know, how
8 volume, how volume will would actually impact that. I
9 don't know that -- we didn't know who would say who
10 agrees or who doesn't agree with either one, the
11 Decatria or the Nona Matrix. I mean we didn't really
12 -- we talked about it and I explained how the Decatria
13 works in comparison to the Nona, I don't know if I
14 said that right, Nona Matrix. So the first two
15 questions, I don't know that we can't -- it doesn't
16 seem like we can answer that because we don't know
17 some of the details.

18 DR. ENGELJOHN: But I would suggest perhaps
19 that's not -- you can look at it differently and
20 instead if -- identify how it could be or should be
21 used. What would be the advantages of one or the
22 other if you had some idea about that. The issue is

1 we're looking for input on how you think volume should
2 factor into the equation.

3 DR. RYBOLT: How volume should factor into
4 the equation. That's why, if you can read it, the
5 equation on the board now as you guys proposed it.
6 Now is Don's -- I guess the question I had is Don's
7 Nona that he presented, that's based on the same
8 equation, right? Using the same at this point?

9 DR. ENGELJOHN: His in essence was not to
10 have -- to divide it into two to come up with one
11 score.

12 DR. RYBOLT: Okay. So using right there.
13 So you're using two different numbers. And how would
14 you -- how would that then -- how would volume factor
15 into that?

16 DR. ENGELJOHN: And I think that's what --

17 DR. RYBOLT: That's what you want us to --
18 so with that --

19 MR. WALDROP: So this Nona Matrix is the new
20 algorithm?

21 DR. ENGELJOHN: It can be a new algorithm.
22 It's a new approach, where again as I think this first

1 -- the second one was you take the two scores and
2 divide them in two and you end up with 20 -- or you
3 could use an independent such that you have a risk
4 control score and then inherent risk, two independent
5 numbers and then factor volume in.

6 MR. ROOP: So what would that formula look
7 like?

8 DR. ENGELJOHN: That's what we're asking
9 you. It all becomes how do you rate these things.
10 There isn't a magic number there. How do you --

11 DR. RYBOLT: Questions, comments? I think
12 risk control should be the most important. Risk
13 control is something the plant has control over, and
14 that's the most important components right now, and I
15 think there are other things that should be included
16 into the risk control but, you know, considering
17 what's there now, this is the most important. As you
18 -- product, the expert elicitation said 1 and if your
19 client is not doing it very well at all, you know, but
20 because of this, this is the safest product, you could
21 be scoring up with this the way it is. I think Joe
22 outlined that today. You could still be in one of the

1 lower or the least inspection categories.

2 How should volume be incorporated? This
3 equation doesn't apply anymore.

4 MR. MEAD: Kevin Mead with Hormel. We
5 pretty much deal with volume as factored with risk.

6 DR. RYBOLT: Factored out?

7 MR. MEAD: Factored with the risk control.

8 DR. RYBOLT: With risk control.

9 MR. MEAD: Whether it be interventions that
10 are being used. Maybe each -- we've got five
11 different types of categories being produced and each
12 one may have risk control measures that volume needs
13 to be factored in there somewhere in overall plants,
14 risk to public health. Specifically, exactly how
15 that's --

16 DR. RYBOLT: How that's incorporated. I
17 agree and how to do that, I don't know. I still --
18 called me and asked me to facilitate one of these
19 group, and I was constantly asking how this is going
20 to work but I've done it certainly myself, looked at
21 the ratings, and just simply move the volume over to
22 here. I changed it from a 1 to 5, to a 1 to 3, I

1 changed it from 1 to 10, you know, and what we're
2 talking about here is some sort of credits. If you're
3 final RBI was a certain percentage or risk control
4 measure was a certain percentage below whatever, then
5 you get some sort of credit on your final RBI to help
6 bring your RBI down some. But volume was still
7 factored into the equation.

8 Chris, you asked a question earlier should
9 volume be used essentially when you were asking about
10 the risk assessments and all that, Carol --

11 MR. WALDROP: I mean the reason we were
12 asking that question is because it seems to make sense
13 that it should be used, you know, common sense tells
14 you that it has to be factored in somehow but I
15 haven't seen where -- I'm not aware of any -- I'm not
16 risk assessor myself. So I haven't done any sort of
17 risk assessments that tell me what the impact on
18 public health will be and how you include this in
19 either side. And that's kind of what I wanted to get
20 answers from.

21 DR. ENGELJOHN: Well, Chris, if I may expand
22 just a little bit on what Janell was trying to say in

1 terms of ultimately how that works in terms of a fine
2 model. We would identify whatever data have on the
3 seven factors or whatever, and you would plug them
4 into an algorithm and have whatever your public health
5 data. So if you chose to take last year's data and
6 plug all the information in on that, just to see what
7 would happen, you run it with weighting volume at 10
8 percent, you know, versus 20 percent versus 30
9 percent, and each of these factors weighted
10 differently. Then you run this model through several
11 hundred thousand integrations and you go through some
12 statistical processing and it comes out with some
13 distribution of, of -- in essence, you can then
14 discern which factor had the greatest impact on
15 controlling -- so public health impact, and use the
16 CDC data for 2005 as best we can relate it to the
17 parts that regulate. What that is, if you wanted to
18 make sure that you held that constant or wanted it to
19 be more effective or less. Then you see which factor
20 had that impact and then that's one way you establish
21 through that process what the weight should be, so
22 that you could insure based on that model what had the

1 most impact on the controlling your amount of volume.
2 So that's how you would run a risk assessment model,
3 or should be done, but in the absence of having -- you
4 can do that for a condition forward, which is the
5 Agency would be doing, constantly checking that
6 against its history to see what happened, and
7 establish those based on that when we can do the risk
8 assessment forward. Does that make a little more
9 sense?

10 MR. WALDROP: I think so. And if you did it
11 on say 2005 data, wouldn't that give you some of the
12 information that you're looking for, that you're
13 asking for us to provide here? Wouldn't that kind of
14 tell you where volume might be best put in, at what
15 level?

16 DR. ENGELJOHN: We could, except that
17 putting all things together, we don't have as good
18 attribution data to be able to say here's what the
19 effect was from *Salmonella*. We could make some
20 predictions about that. We know better information
21 about the -- we actually have a risk assessment where
22 we can actually do this and show that. 0157, we had

1 an old risk assessment that hasn't been updated with
2 the newest information but that's what we're trying to
3 update. So you can do that for one or two pathogens
4 but not the whole system. We ultimately want to be
5 able to do it for all systems. So we started out
6 based on the current information. So that would be
7 the kind of information that we could present in terms
8 of here's what the past data has said. Ultimately we
9 need this new information or we need better
10 information here to cover a broad range, but our view
11 is that the data that we have that's being used now is
12 what we would base it on. And right now you don't
13 have good data. You use your best judgment. That's
14 why we, in combination with the expert elicitation,
15 what parts would be regulated. And then in some
16 fashion, you know, which pathogens they have in them
17 and you run that model. So you use your best judgment
18 in the absence of having better data, which we will
19 have in the future. Does that help?

20 MR. WALDROP: A little bit, yeah.

21 MR. VARDON: Peter Vardon with FDA. Another
22 alternative would be to just take the average IR plus

1 RCM times the volume factor. I can see the logic of
2 having volume with the inherent risk but also with the
3 risk control. And because there's a certain logic,
4 you just take the average and then times the volume.

5 DR. RYBOLT: That's what you're saying?

6 MR. VARDON: Yeah. Because I agree a high
7 volume plant --

8 DR. RYBOLT: Does that make the third axis?

9 MR. VARDON: What's that?

10 DR. RYBOLT: Does that make it the third
11 axis? Go ahead.

12 MR. VARDON: It might be but another
13 important issue is whether you have seasonal variation
14 or variation around the peak production volume, and I
15 would think that if we have a low production season,
16 we probably will have lower intensity inspection but
17 you would want to control for that variation volume.

18 DR. RYBOLT: Okay. Any thoughts, comments
19 on this?

20 MR. ROOP: Well, I still think it's putting
21 too much weight on volume.

22 DR. RYBOLT: That's what I was just

1 thinking, but I may be wrong. My intuition says that
2 that actually gives more weight to volume.

3 MR. ROOP: It still makes volume a direct
4 multiplier

5 DR. RYBOLT: Yes, sir.

6 DR. BASU: Pat Basu with APANA. I'm going
7 to go back to my capacity, where I was before and I
8 was involved setting up large plants, intervention
9 measures a long time ago, before I get transferred,
10 and most of the larger plants that I worked with,
11 Tyson, you know, all the very big plants, you know,
12 the bigger the volume, the more money they had to
13 spend on interventions and they did a fantastic job in
14 creating and coming up with new things like the steam
15 pasteurization and all that stuff. So to me volume is
16 not as important as looking at the risk intervention
17 factors the plant is using, to make sure we have less
18 products that can affect the public. I was involved
19 with a state program in West Virginia for nine years.
20 I've been in very, very small plants and know, you
21 know, we had one to one inspection sometimes, and
22 sometimes those plants were very, very good and some

1 of them were not. So the volume didn't matter. It
2 was the part of the plant's system control that
3 mattered more than anything else, and I've been in
4 many large plants throughout this country, most of
5 them throughout this country, and I've seen very nice
6 large plants, and I've been pretty bad large plants
7 which were in "60 Minutes." I was in the plant that
8 was -- on "60 Minutes" a long time ago. I was there
9 before it was focused and I reported that. It's in
10 the record and the point is, it's the plant's attitude
11 or the company's attitude to advance these measures
12 and use interventions that will have more inspection
13 or less inspection. A plant like -- should have 20
14 inspectors whereas a plant of double the size would
15 have 2 inspectors. That's on the factor that's
16 affecting the public, the number of inspectors. It's
17 how good the product is being prepared and how good
18 it's being corrected, the problems coming in. I'm not
19 saying put the pieces in there and then take it out.
20 I'm saying all the factors considered, intervention is
21 an important factor to me, more than volume is.

22 DR. RYBOLT: I don't remember everybody's

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1 name. We've had discussions about NRs and volume, a
2 plant, a large plant, a large volume plant has an
3 opportunity to have more NRs because they have more
4 tasks to perform, which there has been some
5 discussion. We don't know -- we're not going to make
6 that argument. I'm trying to facilitate discussion
7 here. So --

8 MR. PAINTER: Stan Painter, National Joint
9 Council. In working in plants, I've saw plants that
10 produced many complex products, that did blending,
11 grinding, mixing, use of restricted ingredients, fully
12 cooked, par fry, you know, hundreds of employees, and
13 I go in there, and there was one task, one task cannot
14 perform. So, you know, you can't go by the number of
15 NRs produced besides in the plant. And I've went down
16 the road and there's a small plant that had like six
17 or eight tasks to perform, and it's like what's up
18 with this. You know, there's no rhyme or reason to
19 the way the plants come up and the tasks that are
20 produced. So, you know, your NRs are going to be a
21 reflection of some how for the size of the plant based
22 on the product that's produced.

1 DR. RYBOLT: So that's an outcome of RBI
2 that would be addressed.

3 DR. ENGELJOHN: Just again, maybe just some
4 food for thought here, but the Nona Matrix that the
5 Agency presented was to again do the inherent risk
6 measure and the risk control measure as independent,
7 so that they're not averaged is what we did. In this
8 case then, whatever factors you would have in inherent
9 risk, whatever factors you have in risk control,
10 plants that -- you would weight those with numbers
11 that would be initially assigned whatever weighting
12 consensus we've come up with as being what needs to be
13 there in the absence of having better models
14 information. Such that there are in essence three
15 levels within each of those, so that you're crossing
16 the combinations of the information are three
17 differing levels, in order to come up with what we
18 have here. So that the goal being that any plant can
19 be moved from one level to the other, which we believe
20 to be what we heard from the last meeting was, it was
21 important for the plants to know that they didn't keep
22 the level of inspection that they have based on

1 performance. So that's the goal.

2 DR. RYBOLT: And vice versa. Small plants
3 have the opportunity to move all the way to the other
4 side, to a category 3 or a level of inspection 3,
5 whatever you call it, like Joe said today and I think
6 Felicia actually made that comment at the last meeting
7 as well.

8 MS. BLUMBERG: Just to let you know, we have
9 15 minutes.

10 DR. RYBOLT: We have about 15 minutes here.
11 How much do we want volume to count?

12 MR. PAINTER: Well, you know, we have --
13 this Stan Painter with the National Joint Council. We
14 haven't looked at how we've gotten that information.
15 Where Dan said earlier that, you know, due to the
16 complex process we can't make the plants give us that.
17 So I'm an inspector in Plant XYZ, and I need this
18 information. How am I going to get it? It's not on
19 the precip reviews. Am I going to have to develop an
20 individual that keeps up that, another tool? How
21 often am I going to have to get that information as an
22 inspector? How long will I have to compile that and

1 get it to someone? Who am I going to give that to?
2 Am I going to send it to my supervisor? Am I going to
3 send it to the District? Am I going to send it to
4 Washington? And then after I send it, how long is it
5 going to take the Agency to compile that information
6 to determine whether I can move from level 1 to level
7 2 to level 3? You know, it's, it's, you know, there's
8 just a number of questions I have regarding the whole
9 thing. You know, we're talking about volume but we
10 haven't talked about how we're going to get that
11 volume.

12 DR. RYBOLT: That's question number 3. How
13 are we going to get that information?

14 DR. ENGELJOHN: And the Agency's proposal
15 was that in the PBIS extension where the plant profile
16 is, is that gets updated as often as the often as the
17 inspector updates it. Our goal is to insure that the
18 inspectors in the facilities know what's being
19 produced and have some general ideas how much is being
20 produced. And it's the general idea that we're asking
21 for, the approximation is what was requested. And the
22 PBIS gets updated in terms of synchronization as

1 frequently as synchronization occurs, and then the
2 plant score as the Agency had proposed would be a once
3 a month thing. That's also something that's up for
4 comment, that the issue would be to have some general
5 relative understanding of what's being produced in
6 that operation at any given time.

7 MR. WALDROP: Dan, hasn't the Agency or
8 Dr. Raymond said that you guys want to be able to
9 change the level of inspection on a daily basis?

10 DR. ENGELJOHN: And in the process, by
11 having this information, the new information out
12 there, again the system the Agency has right now is
13 the PBIS which in part is dependent upon when the
14 information is entered and when it's synchronized so
15 that it goes into the database and then that
16 calculation is done which can be automated. So that
17 automated calculation occurs as frequently as it needs
18 to.

19 MR. WALDROP: So that means the inspectors
20 would have to check the volume on a daily basis?

21 DR. ENGELJOHN: I think the issue would be
22 know generally what happens in that operation and we

1 characterize this first one as what has occurred in
2 the last 30 days. So we have some general
3 understanding of what's there. What should the
4 questions be and how do we get to those questions
5 would be helpful information and what would be more
6 helpful in the future as we gather that information.
7 Again, it's general changes in terms of -- part of
8 this Nona Matrix was to present three differing levels
9 of inspection. That's relatively speaking, to kind of
10 put some things into some categorization so that there
11 is some -- obviously changes that can occur that can
12 move you from one level to another. From the Agency's
13 resource allocation issue, we need to have some
14 understanding of what occurs in that plant or what is
15 expected to occur over time so we can manage the
16 resources and make sure we have it right by way of
17 inspection of the operation.

18 MR. MEAD: Kevin Mead with Hormel. Whenever
19 I've had a inspector with a PBIS task, they've come to
20 me and ask the questions. I don't know. Maybe that's
21 unusual. I don't know. But every time, over 18
22 years, when they want to know volume, they come to me

1 and I pull up, here's my annual production report.
2 For fiscal 2006, I produced 287 million pounds of
3 whatever it was in the plant, and I give them the
4 information whenever they come to me and ask. It's
5 like when they file the 10240.3. I pull that
6 information off the reports. They may not know how
7 much we ran day 1, day 2, day 3, but we guide them to
8 this is how much we produced on an annual daily basis,
9 and worked with them on that and, you know, and I
10 think Tysons, your inspectors probably ask that of you
11 guys as well.

12 DR. ENGELJOHN: Is that a form or something
13 or is that an industry type of record that you
14 generally have for accounting purposes that we could
15 identify --

16 MR. MEAD: Every plant knows how much they
17 produce from the accounting standpoint.

18 DR. ENGELJOHN: Yes. And so I think what
19 we're asking for is what would be -- where -- what
20 kind of record do you have or where do you have that
21 document so that could serve as a piece of information
22 that we could go to and check?

1 MR. MEAD: It's not something that's public
2 knowledge on a daily basis. They come and ask and
3 then I go -- we go through it and I show them maybe if
4 I produced a million pounds in this particular
5 category.

6 DR. RYBOLT: Okay.

7 MR. MEAD: You know, we're not forced to do
8 that but I think most of us do that because it's not a
9 big deal.

10 MR. PAINTER: Stan Painter again for the
11 National Joint Council. You know, I'm of the opinion
12 that volume is important but I don't want to get into
13 a situation that's, you know, a plant is concerned
14 about how much they're producing and to say, okay, you
15 have us listed as producing 900,000 pounds and now
16 we're down to 500,000 pounds, you know, go in and
17 change that or whatever we're doing, you know, turkeys
18 are seasonal, you know. We're producing turkeys now
19 and now we're only producing, you know, less over a
20 certain period of time. So therefore, you know, the
21 volume is down. Make sure you change that on the
22 PBIS. You know, we're dealing with a pull and tow

1 kind of thing that the plants are concerned on their
2 side about the level, and then it's placing a burden
3 on the inspection staff to have to do what they need
4 to do in order to get it categorized correctly.

5 So, you know, that's something that I don't
6 want the responsibility for my people to have to do as
7 far as to have to keep up with how many pounds a plant
8 runs, you know. Like I said earlier, we've got no
9 idea, the Agency has no idea. They want to use volume
10 but they don't know how to use it, you know.

11 DR. RYBOLT: I think to that you mentioned
12 having the data updated, it would be prudent to have
13 that information updated because if you're producing
14 product here and it's on the list -- you're producing
15 ground turkey here, and then I quit producing it for
16 half a year, it needs to be updated because that's
17 going to change my RBI. So it does have to be
18 updated.

19 MR. PAINTER: It would have to be updated
20 but when do I do that? When do I do that? Do I do
21 that every so often?

22 DR. RYBOLT: That's what we're going to talk

1 about how now. What will we need to do.

2 MR. PAINTER: How often? Who do I report it
3 to?

4 DR. RYBOLT: Suggestions, suggestions, those
5 are suggestions.

6 DR. ENGELJOHN: We want suggestions. I
7 think the PBIS --

8 MR. PAINTER: The circuit supervisor should
9 keep up with that. The circuit supervisor for that
10 circuit should have a concept or grasp of what meat
11 producer XYZ produces and about how much. The circuit
12 supervisor should have to do that himself or herself,
13 and enter the results.

14 DR. ENGELJOHN: And, Stan, I think that's a
15 helpful suggestion. And once a month. We're looking
16 for some input here that so that we have some
17 consistency --

18 DR. RYBOLT: I would think that it would
19 need to be, say if a plant is producing raw ground
20 turkey and they stop producing that, they're going to
21 want to get that updated as soon as possible. So it's
22 going to be almost all the plants. It's similar to

1 the 10240.3 -- when we change alternatives, we have to
2 send in a form to get that updated. That's what we do
3 now. Comments, Rick, Kevin, Chris, anybody else?

4 MR. ROOP: Well, I'll just comment on the
5 update. I think daily updates is a little
6 impractical. So I think it has to be more periodic
7 than that. I agree with your comment that obviously
8 from an operations standpoint, I want an adjustment to
9 be made as soon as practicable, but I don't think
10 that's practical to do that on a daily basis.

11 DR. ENGELJOHN: Well, how often would you be
12 looking at, or would you be changing it daily?

13 MR. ROOP: No, my point is though if I stop
14 -- if I'm producing ground chicken for example at a
15 plant and I stop on a Tuesday, I wouldn't expect the
16 Agency to react to that on Wednesday morning. I think
17 that's not practical.

18 DR. RYBOLT: Yes.

19 UNIDENTIFIED SPEAKER: Would that not --
20 would that include changing the numbers daily --

21 UNIDENTIFIED SPEAKER: Do you disagree?

22 UNIDENTIFIED SPEAKER: We couldn't keep up

1 with that many changes. That would defeat your RBI.
2 It would be --

3 DR. ENGELJOHN: I think that's practicable
4 and feasible and it certainly doesn't jeopardize
5 public health. That's the kind of thing that we want
6 but what's practical now? Just look at it this way,
7 the current system is we have a PBIS system that
8 supposedly schedules tasks on a weekly basis. So
9 here's the level that it's expected to be done over
10 the course of this next week. Is that a reasonable
11 approach? Should it be more frequent, less frequent?
12 Those are helpful suggestions.

13 DR. RYBOLT: Anything else? Do we all
14 agree?

15 MR. PAINTER: Well, let me say this. Let's
16 say that the frontline supervisor, you know, enters
17 this data. They get the data. They get the data from
18 the plant, and it's entered into the system. There
19 needs to be some kind of communication to the plant to
20 let them know that they move from one level to the
21 other as quickly as possible and to the inspector. So
22 notification needs to go to both parties. You know, I

1 don't want to get into a situation and say, you know,
2 plant A, you have a warning, now I'm in level 2 and
3 then, you know, or plant X saying, I'm a level 2 and
4 now we're in level 1. So, you know, that information
5 needs to be distributed to the inspectors and to the
6 plant simultaneously so that everyone knows where they
7 stand and what they need to do.

8 DR. RYBOLT: We do that now with *Salmonella*
9 verifications, *Salmonella* sets, when they use the
10 chart saying they share the data.

11 DR. ENGELJOHN: Well, and I mean you just
12 need samples for *Salmonella* sets. The categorization
13 is set by Washington. It isn't set by the local
14 inspector or the district manager. We make that based
15 on the data that we have. So the appeal for that was
16 coming from Washington. It's a little bit different,
17 but there the sets are set at the completion of two
18 complete sets. So there's -- a finding, and then you
19 get letter from the Agency through the district
20 manager.

21 MR. MEAD: Kevin Mead with Hormel. I agree
22 that at most it would be weekly that you be able to

1 update on each factory. There's no way I could even
2 keep up with the plant doing daily and maybe even
3 weekly is too often. And then from that standpoint, I
4 wouldn't want to wait any longer than a month from an
5 operational standpoint. But there's other things,
6 too, when we talk about notification. At what point
7 do you update your plant profile? How often should
8 that be? If I go and have a new production line, that
9 actually adds say another risk category, you know,
10 maybe I'm going to add another type that's going to
11 add another, how quickly does that have to be entered
12 into the RBI question, and things like that. I don't
13 see anything about how often any of these things
14 should these things be updated into your plant
15 profile.

16 MR. WALDROP: The other side of that is that
17 if you add an intervention, you're going to want that
18 updated pretty quickly because that hopefully will
19 decrease your RBI.

20 MR. MEAD: So it's not just volume updates,
21 how often and how quickly we update the whole picture,
22 you know. I know this is probably NRs, but I agree

1 with the NR policy unless it's a direct product
2 adulteration, we've taken that out of the picture.
3 There's so much variability on the plant that, I think
4 that's one thing we don't like to do.

5 DR. RYBOLT: I was just told we've got to
6 hurry. We've got only a couple of minutes before we
7 have to get back to the other room. Question 4, are
8 there any other suggestions for how to factor in
9 exposure into assessing the risk presented by an
10 establishment?

11 MR. MEAD: Most of the project plants, none
12 of them are slaughter, correct?

13 DR. RYBOLT: That's correct.

14 MR. MEAD: So there's no turkey slaughter,
15 chicken slaughter, and I don't work directly with the
16 poultry but if you have a plant that has a 5 percent
17 *Salmonella* rate or a 15 percent *Salmonella* rate, how
18 does that *Salmonella* rate factor in? If they make 1
19 million pounds, so they're at 15 percent and if they
20 make 50 million it's 5 percent. It gets right back to
21 where it should be in the risk control or some how it
22 should be.

1 DR. RYBOLT: That was -- you're correct.
2 We're not talking slaughter establishments.

3 DR. ENGELJOHN: Right.

4 MR. MEAD: Well, I guess I assume in general
5 that the question is going to be there throughout the
6 entire risk-based inspection, that that's just one
7 thing. The only thing we see would be the *Salmonella*
8 rate, you're at a different level. The *E. coli*,
9 you're talking ground beef, they're listed as options
10 in here. I know they're not the initial protocol but
11 I think you look long term how's volume going to
12 impact all those test results. Just because you have
13 one positive, you know, there's a factor.

14 MR. ROOP: I have a question for you. You
15 said about the possibility of putting volume on the
16 other side of the equation. I'd like to see an
17 example of what you mean by that. How would that
18 affect it?

19 DR. RYBOLT: Essentially what I did, one of
20 the -- is right here. Just like this, 1 through 5
21 system, factored it in along with this.

22 MR. ROOP: Oh, I thought you were putting it

1 on the other side of the equation.

2 DR. RYBOLT: No, no, no. I call this --
3 well, the original. This is two sides of the
4 equation.

5 MR. ROOP: I see.

6 DR. RYBOLT: Sorry. I should have clarified
7 that. The way I did it was instead of having volume
8 times the inherent risk or the number from the expert
9 elicitation, I made that part of the RCM, which they
10 do, they have control over the plant and that's a
11 function of potential exposure. If they have really
12 good controls, volume factors into that, and it allows
13 it to be incorporated but it doesn't put as much
14 emphasis or too much emphasis on it.

15 MR. ROOP: And with that in mind, one of the
16 ideas that I would use to make it less complex is just
17 use the -- of it and factor that in.

18 DR. RYBOLT: Leave it here and use the --

19 MR. ROOP: It's a suggestion. Because
20 really -- there's really no fairness between, you
21 know, 1,000 pounds and 9,999 in terms of scheme of
22 things. So why don't just use the volume. It's a lot

1 simpler, a smaller number to deal with.

2 MR. WALDROP: This is Chris Waldrop,
3 Consumer Federation. Just for the record, I'm not
4 ready to sign off on that until I kind of work through
5 the numbers myself but as a suggestion, it maybe
6 something we should consider.

7 DR. RYBOLT: And even --

8 MR. WALDROP: I'd like to think about it
9 further.

10 DR. RYBOLT: And I moved it here and I've
11 moved it around several different ways to calculate
12 volume. It may be the one that's already in the
13 papers. It may be 1 to 3. It could be 1 to 20. It
14 just depends, you know, how we put that in. Maybe
15 it's a multiplier rather than an addition to that and
16 I think the biggest reason the plant moved it over is
17 because it didn't make sense on this side. It didn't
18 make sense for the inherent risk of the products. In
19 my mind, it makes more sense with the controls of the
20 plant. No matter how risky this product is, if this
21 extremely well, there's not going to be a problem
22 because he's controlling that risk. The volume should

1 be incorporated because there's a difference between a
2 really good plant that produces the most riskiest
3 product in a small volume than a really big plant that
4 produces most of that particular volume. That's why
5 in my mind it makes sense. And over here, if we leave
6 it over here, it doesn't change the final outcome at
7 all. There's very little difference there between
8 those two plants. And it's not a science. It goes
9 down through how this plant has performed in the last
10 year because even with the Nona, it still doesn't get
11 to where I think we're trying to go with risk-based
12 inspection. We call plants with very small inspection
13 intensity. So -- inspection intensity. Where should
14 the inspection intensity be? And we, you know, the
15 data collection, we put it in the system and is it a
16 six month window? I think they're proposing a six-
17 month window.

18 MS. BLUMBERG: Well, I think everybody did a
19 really good job, and we've got all the notes written
20 down, and everything will be on the record and they'll
21 be putting a transcript up on the Internet for
22 everybody.

1 (Whereupon, at 11:48 a.m., the meeting was
2 concluded.)

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C E R T I F I C A T E

This is to certify that the attached proceedings
in the matter of:

PRODUCTION VOLUME AND ITS ROLE

IN RISK-BASED INSPECTION

A CHARGE FROM FSIS: QUESTIONS FOR
CONSIDERATION IN BREAKOUT SESSIONS

GREEN GROUP BREAKOUT

Arlington, Virginia

April 25, 2007

were held as herein appears, and that this is the
original transcription thereof for the files of the
United States Department of Agriculture, Food Safety
and Inspection Service.

Victoria Gudeman, Reporter

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